K073260

510(k) Summary

Applicant: Device Partners International
4305 Enterprise Drive, Suite E
Winston-Salem, NC 27106

MAR 13 2008

Contact Person: Monica Early Dougherty
4305 Enterprise Drive, Suite E
Winston-Salem, NC 27106
Phone: 210-957-2083

Date Prepared: November 20, 2007

Device: Device Trade Name: LiiSA Lever Integrated Interventional System Adaptor™
Device Common Name: Hemostatic Valve
Device Classification Name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Classification: Class II
Product Code: DTL
Regulation Number: 870.4290

Predicate Devices: Predicate devices used to demonstrate substantial equivalence are the CoPilot Bleedback Control Valve marketed by Guidant /Abbott Vascular (K991102) and theY-Click Connector marketed by Elcam Medical (K060759).

Device description: The LiiSA Lever Integrated Interventional System Adaptor™ is an Adaptor designed for use in all interventional applications where a hemostasis valve is required and has an inner diameter of up to 9 F (3.0 mm / 0.118"). It has a seal which can be opened and closed by control of a lever. Pushing the lever will open the seal; releasing the lever will close the seal. The lever can be rested in a partially open position or a fully open position. These positions can easily be identified by the position of the lever and by an audible "click". The lever can be further controlled with great sensitivity to have the optimal seal around the interventional device (i.e., guide wire, balloon catheter, stent). This enables the user to experience a minimum of back bleeding with maximum security for his introduced device. The LiiSA Lever Integrated Interventional System Adaptor™ offers two external arms for the purpose of locking introduced devices (i.e., guide wire) to enable users to introduce additional devices without the need to manually hold and secure the devices already introduced and secured. The LiiSA Lever Integrated Interventional System Adaptor™ has a "Y" side arm to facilitate contrast media injection, saline flush and blood pressure monitoring.

Indication for use: The LiiSA Lever Integrated Interventional System Adaptor™ is a Y-Connector and hemostasis valve which is intended to maintain hemostasis during the introduction, use and withdrawal of diagnostic or interventional

devices (i.e., guide wires, balloon catheters, stents) used in angioplasty procedures. It is compatible with guiding catheters 9 F or smaller and 0.014" – 0.038" guide wires.

Substantial Equivalence: The LiiSA hemostasis valve has the same or similar intended use, indications for use, principle of operation, and performance characteristics as predicate devices and is, therefore, substantially equivalent to the predicate devices.

Performance Data: The safety and effectiveness of the LiiSA hemostasis valve has been demonstrated through data collected from nonclinical bench tests and analysis.

Conclusion: The evaluation of the LiiSA Lever Integrated Interventional System Adaptor does not raise any additional concerns regarding safety and effectiveness and may therefore is considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

Device Partners International
c/o Ms. Monica Dougherty
Director, Regulatory Affairs
4305 Enterprise Drive, Suite E
Winston-Salem, NC 27106

Re: K073260
LiiSA Lever Integrated Interventional System Adapter
Regulation Number: 21 CFR 870.4290
Regulation Name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTL
Dated: January 16, 2008
Received: January 17, 2008

Dear Ms. Dougherty:

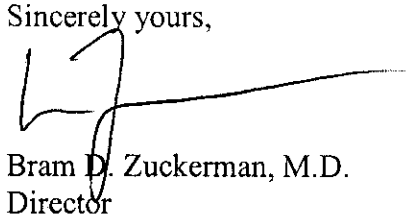
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K073260

Device Name: LiiSA Lever Integrated Interventional System Adaptor™

Indications For Use:

The LiiSA Lever Integrated Interventional System Adaptor™ is a Y-Connector and hemostasis valve which is intended to maintain hemostasis during the introduction, use and withdrawal of diagnostic or interventional devices (i.e., guide wires, balloon catheters, stents) used in angioplasty procedures. It is compatible with guiding catheters 9 F or smaller and 0.014" – 0.038" guide wires.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073260